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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/814,764	FIRST, ERIC R.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *February 13, 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 13-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/20/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-11, 13-19 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections Withdrawn

3. Claims 1-4, 6-10, 12-13 rejected under 35 U.S.C. 102(b) as being anticipated by Pohl et al, herein withdrawn in light of the amendment of the claims to recite the phrase "without reducing spasticity", but would be reinstated upon removal of the New Matter.
1. Claims 1-3, 6-9, 12, and new claim 14 under 35 U.S.C. 102(b) as being anticipated by Kennedy, (1997), herein withdrawn in light of the amendment of the claims to recite the phrase "without reducing spasticity", but would be reinstated upon removal of the New Matter.
2. Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement., in light of the amendment of the claims to no longer recite the phrase "substantially paralyzing".
3. The rejection of all of the claims under 35 USC 112, second paragraph for reciting the term "without substantially paralyzing a muscle", has been obviated in light of the amendment of the claims to no longer recite the phrase "substantially paralyzing".

Rejections Maintained

4. New claims 15-18 as previously applied to claims 1-4, 6-10, 13 under 35 U.S.C. 102(b) as being anticipated by Pohl et al, for reasons of record and responses set forth herein.
5. New Claims 15-17 are rejected as previously applied to claims 1-3, 6-9, and 14 under 35 U.S.C. 102(b) as being anticipated by Kennedy, (1997), for reasons of record and responses set forth herein.
6. Claims 7-11 rejected under 35 U.S.C. 102(b) as being anticipated by Gassner et al (US Pat. 6,44,787) is maintained for reasons of record and responses set forth below.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 13, 2006 has been entered.

Information Disclosure Statement

2. The information disclosure statement filed September 20, 2005 has been considered.

Response to Arguments

1. Applicant's arguments filed May 2, 2005 have been fully considered but they are not persuasive.

7. The rejection of new claims 15-18 as previously applied to claims 1-4, 6-10, 13 under 35 U.S.C. 102(b) as being anticipated by **Pohl et al**, is traversed on the grounds that "Since the Pohl reference teaches the use of botulinum toxin to reduce spasticity of a muscle, and the claimed invention recites the administered botulinum toxin does not cause reduction of spasticity, the Pohl reference cannot anticipate the claims.

8. It is the position of the examiner that the recited intended use of the claimed method of claims 15-18 does not define over the applied prior art, in light of the fact that the preamble does not breath life and meaning into claims 15-18 because the patient to which the botulinum toxin is administered is not so claimed not to have contractures or spasticity, and the term "a patient" is a non-specific article that does not refer back to the preamble that recite the term patient. The methods of claims 15-18 also do not recite a correlation step that corresponds to the preamble of the newly submitted claims.

9. Applicant's traversal is not commensurate in scope with the instantly claimed invention which may administer botulinum toxin to any patient with a pressure sore of any amount, which may reduce spasticity, as the methods step does not correlate to or correspond to the recited intended use of the claimed methods.

10. Claims 15-17 are rejected as previously applied to claims 1-3, 6-9, and 14 under 35 U.S.C. 102(b) as being anticipated by **Kennedy**, (1997), is traversed on the grounds that "Similar to the Pohl reference, the Kennedy reference teaches that a botulinum toxin can be administered to reduce spasticity of a muscle", and asserts that the claimed invention does not cause reduction of spasticity.

11. It is the position of the examiner that the recited intended use of the claimed method of claims 15-17 does not define over the applied prior art, in light of the fact that the preamble does not breath life and meaning into claims 15-17 because the patient to which the botulinum toxin is administered is not so claimed not to have contractures or spasticity, and the term "a patient" is a non-specific article that does not refer back to the preamble that recite the term patient.

12. The methods steps of claims 15-17 also do not recite a correlation step that corresponds to the preamble of the newly submitted claims. Applicant's traversal is not commensurate in scope with the instantly claimed invention which may administer botulinum toxin to any patient with a pressure sore of any amount, which may reduce spasticity, as the methods step does not correlate to or correspond to the recited intended use of the claimed methods.

13. The rejection of claims 7-11 under 35 U.S.C. 102(b) as being anticipated by Gassner et al (US Pat. 6,44,787) is traversed on the grounds that: "Gassner reference does not teach the administration of a botulinum toxin to treat pressure sore. Instead the Gassner reference teaches the administration of the botulinum toxin to enhance wound healing. Further, the "wounds" of

the Gassner reference are not associated with a pressure sore, but are associated with lacerations and bone fracture (the Gassner reference, col. 3, lines 5-36)".

14. It is the position of the examiner that the scope of the claims encompassing treating areas or regions of inflammation to prevent the formation of pressure sores which is defined by Applicant's Specification at page 30, paragraph 2.

15. One embodiment provided by Gassner et al is the administration of botulinum toxin to an unfavorable wound (Gassner et al, claim 26, col. 10), the unfavorable wound being defined to be a skin wound (col. 3, line 6), to include inflammatory lesions (see col. 3, line 6) and other lesions adversely affected by muscle tension or movement (col. 3, lines 7-8) and is not limited to laceration and bone fracture wounds as asserted by Applicant's representative.

16. Applicant asserts that Gassner et al does not disclose all of the features of the claims.

17. It is the position of the examiner that Gassner et al discloses and claims the methods step of locally administering (see claim 1) an effective amount of botulinum toxin (see claims 2-4) to an unfavorable wound (see claim 26) which is defined to be a region of inflamed skin that needs wound healing (see Gassner et al, col. 4, lines 45-48 "local administration: col. 1, lines 44-55; col. 1, lines 64-65; col. 3, lines 5-8; col. 3, lines 40-41).

The dose of locally administered botulinum toxin is in a therapeutically effective amount of botulinum toxin (see col. 3, lines 66-67 and col. 4, lines 1-4), as well as 7 units and 20 units of botulinum toxin. The instant claims administer between 1 and 3000, and 1 and 25,000 units of botulinum toxin of any serotype and is now claimed to be "without reducing spasticity of a muscle". Clearly the amount of Gassner et al is at the lower end of the number of units of

botulinum toxin now claimed and would therefore produce the same claimed effect of "without reducing spasticity of a muscle" .

Applicant has defined the range of botulinum toxin that may be administered locally to encompass botulinum toxin doses of 1 to 3000 units or 1 to 25000 units of any botulinum toxin to be doses that would be administrable to a patient "without reducing spasticity of a muscle". Gassner et al while not disclosing or describing this functional characteristic, by all comparable data, and the combination of claim limitations set forth to claim Applicant's invention, Gassner et al anticipates the instantly claimed invention because Gassner administers a reduced dose locally administered to prevent negative effects on wound healing associated with repeated microtrauma, caused by continuous displacement of injured tissue (see Gassner et al, col. 1, lines 44-55), which results in reduced inflammation, prevention of wound dehiscence together with enhanced would healing (see col. 3, lines 37-42). Gassner et al still anticipates the instantly claimed invention as now claimed.

New Claims/New claim limitations/New Grounds of Rejection

Claim Rejections - 35 USC § 112

18. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

19. Claims 1-11, 13-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

20. Claims 1-11, 13-14 have been amended to recite the phrase ""without reducing spasticity of a muscle, thereby treating a pressure sore" which has been asserted to find original descriptive support in lines 14-18 on page 23 of the instant Specification.

21. The examiner upon consideration of the narrative found at page 23, lines 14-18, could not find the phrase "without reducing spasticity of a muscle, thereby treating a pressure sore" at this location.

Analysis of Claimed invention relative to Original Descriptive support

- The patient of Claims 1-11, 13-14 may be a patient with or without a spasticity condition.
- The patient of Claims 1-6, 13-14 have a pressure sore.
- The patient of Claims 7-11 that do not have a pressure sore, but have a pressure point (inflammation, redness).
- The patient of Claims 1-11, 13-14 may receive about 1 to about 3000 units or 1 to 25000 units of botulinum toxin.
- The spasticity patients of Claims 1-11 and 13-14 , <u>are claimed</u> not to experience a reduction spasticity of a muscle upon the local administration of the botulinum toxin.
    - This combination of claim limitations does not evidence original descriptive support in the instant Specification at page 23, lines 14-18, because spasticity patients are disclosed to be administered a Clostridial toxin at a higher dose to paralyze a muscle.

22. The narrative found at page 23, lines 14-18 defines a genus of methods of treating a pressure sore.

- Two embodiments <u>paralyze a muscle</u>, the two embodiments are related to "contractures or **spasticity**".

- The other embodiment utilizes a dose of Clostridial toxin that is "less than the amount of toxin used to paralyze a muscle" so "not to paralyze a muscle".

The narrative at page 23, lines 14-18 permits administration of botulinum toxin to cause:

- paralysis of a muscle associated with spasticity (see instant Spec. p. 23, lines 14-15); or
- administration of a dose less than the amount of toxin that would be used to paralyze (see lines 16-18) a muscle, for the purpose "not to paralyze a muscle" when the condition is not **associated with spasticity**,

The combination of claim limitations now recited in the Amended claims does not find original descriptive support in the Instant Specification. The instantly claimed genus of methods that administer any therapeutically effective amount of botulinum toxin "without reducing spasticity of a muscle, thereby treating a pressure sore" could not be found in the instant Specification for the reasons set forth above. Therefore amended claims 1-11 and 13-14 contain New Matter.

1. Claims 1-11, 13-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

2. The claimed invention encompasses the administration of 3000 units of botulinum toxin to a patient, as well as encompasses the administration of doses to about 25,000 units of botulinum toxin to a patient.

Brin (1997) teaches that a dose of nearly 3000 Units of botulinum toxin would be a lethal dose in human (see page S155, col. 2, paragraph 2).

Administration of a lethal dose of botulinum toxin to a patient would not serve to treat a pressure sore, nor would it serve to prevent the formation of a pressure sore when the patient is dead. Therefore the claimed invention is not enabled for the administration of doses of about 3000 units or more to a patient in the claimed methods of treating a pressure sore or preventing a pressure sore.

Claim Rejections - 35 USC § 102

3. Claims 7-11, 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Borodic (PG-Pub 2002/017164). (The term "treating" is being read to encompassing prevention and pre-existing conditions; Borodic treats to prevent)

Borodic discloses the instantly claimed invention directed to a method that comprises the step of:

Administering locally (topically, see Borodic claim 12) to a patient a therapeutically effective amount (see page 5, [0048 "20-40" units]) of botulinum toxin (see Borodic claim 5 and claim 10 and page 5, [0050, type A, C and C2]), the amount being that which functions "without reducing spasticity of a muscle (see Borodic claim 6 "produces substantially no muscular weakening"), the local administration being to a pressure point (see Borodic claim 19"inflammation, pain, edema, redness and itching"). Borodic anticipates the instantly claimed invention as now claimed.

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

5. Brin (1997), Muscle and Nerve, Supplement 6, pages s208-s220, Table 2, page S210, teach the prevention and treatment of pressure sore reduction with botulinum toxin.

6. US006429189B is cited to show the treatment of inflammation, redness and edema with botulinum toxin C2, without muscle weakness.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
May 4, 2006

L. R. F. Smith

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